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Gregory D. Ferraro
Novartis
Corporate Intellectual Property
One Health Plaza Building 104
East Hanover, NJ 07936-1080

In Re: Patent Term Extension
Application for
U.S. Patent No. 5,559,111

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,559,111, which claims the human drug product TEKTURNA® (aliskiren hemifumarate), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,204 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 1,204 days.

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of May 2, 2008 (73 Fed. Reg. 24295). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} \text{ (Testing Phase)} + \text{Approval Phase} \\ &= \frac{1}{2} (1,637 \text{ days}) + 386 \text{ days} \\ &= 1,204 \text{ days (3.3 years)}\end{aligned}$$

Since the regulatory review period began August 22, 2001, after the patent issued (September 24, 1996), the entire regulatory review period has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

Neither the limitations of 35 U.S.C. § 156(g)(6) nor 35 U.S.C. § 156(c)(3) operate to reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.: 5,559,111

Granted: September 24, 1996

Original Expiration Date¹: April 4, 2015
Applicant: Richard Göschke et al.
Owner of Record: Novartis Corporation
Title: δ-Amino-γ-hydroxy-ω-aryl-alkanoic acid amides
Product Trade Name: TEKTURNA® (aliskiren hemifumarate)
Term Extended: 1,204 days
Expiration Date of Extension: July 21, 2018

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Hatch-Waxman PTE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450.
By FAX: (571) 273-7755

Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7755.



Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

RE: TEKTURNA® (Aliskiren
hemifumarate)
Docket No.: FDA-2007-E-0282

Attention: Beverly Friedman

¹Subject to the provisions of 35 U.S.C. § 41(b).